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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,751	07/20/2001	Paul Kenneth Rand	PG3604USW	8846

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EXAMINER	
PATEL, MITAL B	

ART UNIT	PAPER NUMBER
3743	4

DATE MAILED: 10/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/889,751	Applicant(s) RAND, PAUL KENNETH	
	Examiner Mital B. Patel	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 July 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 July 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Specification

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a **single paragraph** on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-39 and 41-43 rejected under 35 U.S.C. 102(b) as being anticipated by Davies et al (GB 2242134).

4. **As to claim 1**, Davies teaches a medicament cartridge for use in an inhalation device comprising a carrier **401** having a plurality of medicament retainers **402** in a spiral path arrangement (**See Figs. 13-16**).

5. **As to claim 2**, Davies teaches a medicament cartridge wherein the carrier is substantially planar (**See Figs. 13-16**).

6. **As to claim 3**, Davies teaches a medicament cartridge wherein the carrier is substantially rigid (**See Figs. 13-16**).

7. **As to claim 4**, Davies teaches a medicament cartridge wherein the carrier is circular in shape and is rotationally mountable (**See Figs. 13-16**).

8. **As to claim 5**, Davies teaches a medicament cartridge wherein each medicament retainer comprises a pocket **402** (**See Page 17**).

9. **As to claim 6**, Davies teaches a medicament cartridge wherein a seal is provided to each pocket (**See Page 17**).

10. **As to claim 7**, Davies teaches a medicament cartridge wherein the seal comprises a sealing tape **404** arranged along the spiral path and wherein each pocket is accessible by progressive removal of the tape from the spiral path.

11. **As to claim 8**, Davies teaches a medicament cartridge wherein each medicament carrier comprises a hole **402** in the carrier.

12. **As to claim 9**, Davies teaches a medicament cartridge wherein each hole is provided with a mesh for retention of medicament (**See Page 5 for materials**).

13. **As to claim 10**, Davies teaches a medicament cartridge wherein the carrier is elongate, storable in a flat spiral configuration and extendable as a helix (**See Fig. 16**).

14. **As to claim 11**, Davies teaches a medicament cartridge wherein the medicament retainers are serially arranged along the elongate carrier (**See Fig. 16**).

15. **As to claim 12**, Davies teaches a medicament cartridge wherein each medicament retainer comprises a cavity **402** in the elongate carrier.

16. **As to claim 13**, Davies teaches a medicament cartridge wherein a seal is provided to each cavity.

17. **As to claim 14**, Davies teaches a medicament cartridge wherein the seal comprises a sealing tape **404** and each cavity is individually accessible by peelable removal of the sealing tape.

18. **As to claim 15**, Davies teaches a medicament cartridge wherein each medicament retainer is sized to retain a single dose of medicament (**See Page 5**).

19. **As to claim 16**, Davies teaches a medicament cartridge having from 60 to 500, preferably from 100 to 300, medicament retainers (**See Page 6**).

20. **As to claim 17**, Davies teaches a medicament cartridge wherein the medicament dose is applied to the carrier by wet or dry printing methods. It should be noted that the claim is directed to a device/apparatus and as such patentable weight is given to the end product and not the process. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

21. **As to claim 18**, Davies teaches a medicament cartridge wherein the medicament is present in one or more of the medicament retainers (**See Fig. 16**).

22. **As to claim 19**, Davies teaches a medicament cartridge for use in an inhalation device comprising an elongate carrier having a plurality of medicament doses thereon, wherein the doses are in a spiral path arrangement (**See Fig. 16**).

23. **As to claim 20**, Davies teaches a medicament cartridge wherein the elongate carrier is storable in a flat spiral configuration and extendable as a helix (**See Fig. 16**).

24. **As to claim 21**, Davies teaches an inhalation device comprising a housing **410** having an air inlet **140,121**, an air outlet **420** and an airway therebetween; a medicament carrier **401** having a plurality of medicament retainers in a spiral path arrangement; and a mover **416,470,471** for moving the medicament carrier relative to the housing so as to bring successive medicament retainers individually into communication with the airway.

25. **As to claim 22**, Davies teaches an inhalation device wherein the medicament carrier is a substantially rigid circular disk which is rotatable relative to the housing (**See Fig. 16**).

26. **As to claim 23**, Davies teaches an inhalation device wherein the circumference of the disk is provided with teeth **472** and the teeth engage a worm driver **473,475** for drivable rotation of the disk.

27. **As to claim 24**, Davies teaches an inhalation device wherein each medicament retainer comprises a pocket in a first face of the disk.

28. **As to claim 25**, Davies teaches an inhalation device wherein the second face of the disk has a spiral track for receipt of a tracking pin fixedly mounted on the housing

such that as the disk rotates relative to the housing the tracking pin moves along the spiral track and the disk moves translationally relative to the housing (**See Fig. 16**).

29. **As to claim 26**, Davies teaches an inhalation device comprising a housing **410** having an air inlet **140,121**, an air outlet **420** and an airway therebetween; a medicament carrier **401** having a plurality of medicament retainers **402** in a spiral path arrangement, each medicament retainer having a seal **404**; an actuator **416,470,471** for progressively unsealing each medicament retainer on the spiral path.

30. **As to claim 27**, Davies teaches an inhalation device additionally comprising a mover **472,473,475** for moving the medicament carrier relative to the housing so as to bring successive medicament retainers individually into communication with the airway.

31. **As to claim 28**, Davies teaches an inhalation device wherein each medicament retainer comprises a pocket **402**.

32. **As to claim 29**, Davies teaches an inhalation device wherein the seal comprises a sealing tape **404** arranged along the spiral path and wherein each pocket is serially accessible by peelable removal of the tape.

33. **As to claim 30**, Davies teaches an inhalation device wherein an end of the sealing tape connects to the actuator and peelable removable of the sealing tape is achievable by movement of the actuator (**See Pages 18-19**).

34. **As to claim 31**, Davies teaches an inhalation device wherein the actuator is rotatable relative to the housing such that rotation of the actuator results in coiling of the tape around the actuator (**See Pages 18-19**).

35. **As to claim 32**, Davies teaches an inhalation device wherein the actuator is an axially mounted tapered pole (**See Pages 18-19**).

36. **As to claim 33**, Davies teaches an inhalation device comprising a housing **410** having an air inlet **140,121**, an air outlet **420** and an airway therebetween; an elongate carrier **401** having a plurality of medicament retainers **402**, wherein the elongate carrier is storable in a flat spiral configuration; and a mover in communication with the elongate carrier for helically extending the elongate carrier such as to successively move each medicament retainer to access position.

37. **As to claim 34**, Davies teaches an inhalation device wherein each medicament retainer comprises a cavity in the elongate carrier.

38. **As to claim 35**, Davies teaches an inhalation device wherein each medicament retainer has a seal **404**, the device additionally comprising an actuator **416,470,471** for unsealing a medicament retainer at the access position.

39. **As to claim 36**, Davies teaches an inhalation device wherein the seal comprises a sealing tape **404** arranged along the elongate carrier and wherein each successive cavity is accessible by peelable removal of the tape from the elongate carrier.

40. **As to claim 37**, Davies teaches an inhalation device wherein an end of the sealing tape connects to the actuator and peelable removal of the sealing tape is achievable by movement of the actuator relative to the elongate carrier (**See Pages 18-19**).

41. **As to claim 38**, Davies teaches an inhalation device wherein the mover is rotatable relative to the housing such that rotation of the mover results in coiling of the tape around the actuator (**See Pages 18-19**).

42. **As to claim 39**, Davies teaches an inhalation device wherein the mover is an axially mounted tapered pole and the actuator is also an axially mounted tapered pole (**See Pages 18-19**).

43. **As to claim 41**, Davies teaches an inhalation device comprising a housing **410** having an air inlet **140,121**, an air outlet, and an airway therebetween; an elongate carrier **401** having a plurality of doses thereon, wherein the elongate carrier is storable in a flat spiral configuration; and a mover **472,473,475** in communication with the elongate carrier for helically extending the elongate carrier such as to serially move each does to an access position.

44. **As to claim 42**, Davies teaches an inhalation device wherein the air outlet is provided with a mouthpiece **420**.

45. **As to claim 43**, Davies teaches the use of an inhalation device for the administration of medicament to a patient.

46. Claims 26 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Everett (EP 0469814).

47. **As to claim 26**, Everett teaches an inhalation device comprising a housing **12** having an air inlet **23**, an air outlet **22** and an airway therebetween; a medicament carrier **39** having a plurality of medicament retainers **41** in a spiral path arrangement,

each medicament retainer having a seal **See Col.3, line33** ; an actuator **See Col. 3, lines 46-56** for progressively unsealing each medicament retainer on the spiral path.

48. **As to claim 40**, Everett teaches an inhalation device wherein the actuator comprises a piercer **31** for piercably unsealing a medicament retainer.

Conclusion

49. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6536427, US 6378519, US 6032666, US 5694920, and US 5590645.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 703-306-5444. The examiner can normally be reached on Monday-Friday (8:00 - 4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on 703-308-1957. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

mbp

WEILUN LO
SUPERVISORY PATENT EXAMINER
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